BEHQ-96-13626 49960000 106 PUBLIC NOTICE COPY

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April 10, 1996



CERTIFIED MAIL
RETURN RECEIPT REQUESTED
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OPPT Document Processing Center (7407)
ATTN: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics (OPPT)
US Environmental Protection Agency
Washington, DC 20460

RE: TSCA Section 8(e) Notice

Dear Sir or Madam:

This notice is being submitted by Rhône-Poulenc Ag Company (RPAC) to the Environmental Protection Agency (EPA) in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), 15 USC § 2607 (e).

We are submitting results on a variety of compounds from the same chemical family that are being screened for research and development purposes. Only limited quantities of these compounds have been synthesized.

RPAC claims the alpha-numeric designations and the specific chemical identities of the substances at issue to be confidential business information (CBI). The chemical substances may be nonconfidentially identified as a "heterocycles".

In one type of screening study involving repeated dosing, groups of five male mice were administered a test substance suspended in corn oil as follows:

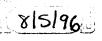
10 mg/kg/day on Days 1 to 4

20 mg/kg/day on Days 5 to 8

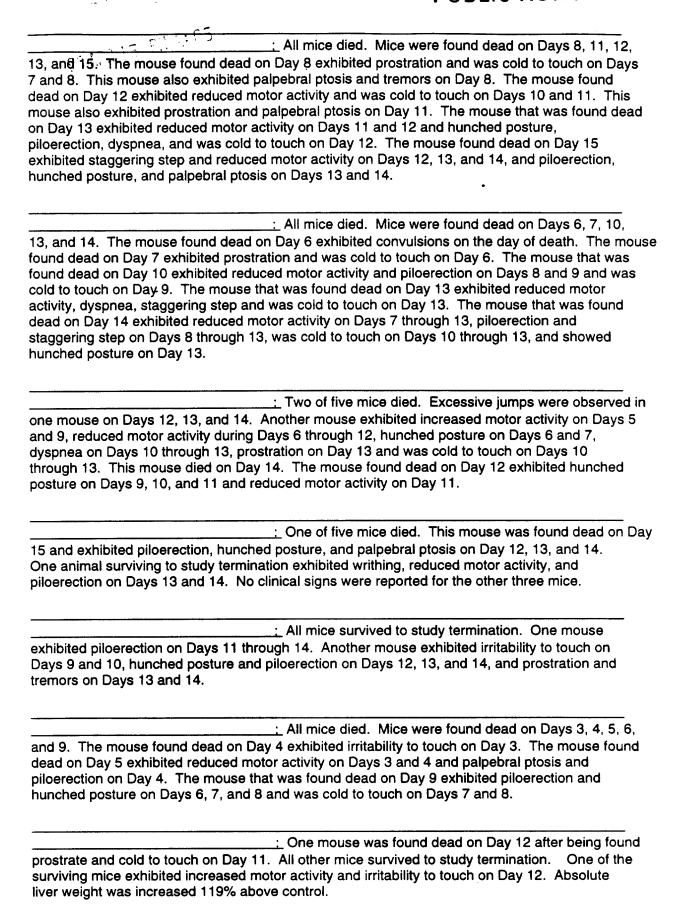
40 mg/kg/day on Days 9 to 12

Surviving animals were sacrificed three days after the last dose administered on Day 12. Information on the following compounds is being submitted based on the observation of clinical signs on several occasions in several animals or increased liver weights. Most animals died within a few days of exhibiting clinical signs. However, in a few instances, animals displaying clinical signs survived until study termination.

	; All mice survived to study termination and no clinical	
signs were reported.	Absolute liver weight was increased 113% above control.	



September 2000



; All mice survived to study termination and no clinical signs were reported. Absolute liver weight was increased 151% above control.
; All mice survived to study termination and no clinical
signs were reported. Absolute liver weight was increased 128% above control.
In another type of screen, a single bolus dose of 100 mg/kg was administered by gavage to five fasted male mice on Study Day 1. Mice were observed daily for clinical signs of toxicity and mortality, and any surviving animals were sacrificed 14 days after dosing. Information on the following compounds is being submitted based on the observation of clinical signs on several occasions in several animals. Most animals died within a few days of exhibiting clinical signs. However, in a few instances, animals displaying clinical signs survived until study termination.
Day 10. The mouse found dead on Day 8 was prostrate and cold to touch on Day 7. No clinical signs were reported for the mouse found dead on Day 10. Three mice surviving to study termination exhibited reduced motor activity, staggering step, piloerection, or prostration on several days.
: One mouse died. Several mice exhibited reduced motor
activity, prostration, hunched posture, piloerection, and staggering step for several days.
: All mice survived to study termination. Tremors,
piloerection, and hunched posture were observed in one mouse on Day 1. Polypnea and tremors were observed in another mouse on Days 1 and 2. No other clinical signs were observed.
Day 14. The mouse found dead on Day 14 exhibited staggering step, reduced motor activity, dyspnea, palpebral ptosis, and was cold to touch for several days. Two mice surviving to study termination exhibited tremors, hunched posture or staggering step, and piloerection on Day 1 and reduced motor activity on Days 2, 3, and 4.
: All mice survived. Hunched posture, staggering step, and
reduced motor activity were observed in all of the mice on the day of dosing only.
prostration, and reduced motor activity were observed in several mice on several occasions prior to death.

SUPPORT INFORMATION OF CONFIDENTIALITY CLAIMS

1. Claims of confidentiality are being made on behalf of RPAC.

- 2. RPAC asserts this claim of confidentiality until such time as a specific chemical is approved for use in the United States. In the event that the chemicals are never approved, RPAC asserts that the CBI information should be provided permanent protection. The structures and use of the chemicals are unique. Disclosure of this information would provide our competitors with information on facets of our business that would be detrimental to our competitive position.
- 3. The information claimed as confidential has not been previously disclosed to any other governmental agency or to EPA.
- 4. This information has been disclosed to only a very limited number of investigators outside of RPAC who have performed either toxicity or efficacy testing. These individuals operate under a strict secrecy agreement. Any individuals who may work with the chemicals will have all health/toxicology information disclosed to them as well, but only on the basis of strict secrecy and respect for the CBI nature of the information.
- 5. Any individuals to whom the CBI is revealed are warned of the nature of the information. Further, they are informed of their obligations to maintain secrecy should they terminate their employment with RPAC.
- 6. None of the information claimed as confidential appears in or is referred to in any advertising or promotional materials for the chemical or the end product containing it, professional or trade publications, or any other media available to the public or to our competitors. Appropriate warnings do appear on safety data sheets, as RPAC considers that individuals who are requested to work with the chemicals have every right to know as much about the chemicals' toxicity as possible. Further, the information is only considered to be CBI with respect to the general public, insofar as our competitors could use the information in an unfairly competitive nature.
- 7. No previous confidentiality determinations have been made by EPA, other Federal agencies or courts in connection with this information.
- 8. RPAC believes that disclosure of this information to the general public would be likely to result in substantial harm to its competitive position. Disclosure of the alpha numeric designations and chemical names would provide some competitors with information about the specific chemistry of this area of our research and our business. Further, the type of toxicological testing being reported in the TSCA 8(e) notice would provide competitive information about this chemical's status in the research and development process and, therefore, the time remaining until commercialization.
- 9. A patent has not been issued for the specific chemical structures. However, the generic chemical structures are covered by a patent that is currently pending.
- 10. The chemicals are not available commercially. They are in the earliest stages of research and development for pesticide use and are unlikely to be developed into commercial products.
- 11. We believe that disclosure of the chemical names would allow a competitor to synthesize these chemicals. RPAC has invested a large amount of time and money into research of the particular chemical family, and information on specific chemical structures would harm our competitive position.
- 12. Disclosure of the chemical structures might reveal information on processes used to synthesize these compounds.

- 13. CAS numbers for these chemicals have not yet been assigned.
- 14. Currently, the chemicals are not the subject of FIFRA regulation or reporting.

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

Glenn S. Simon, PhD, DABT

Director of Toxicology

Triage of 8(e) Submissions

Date sent to triage: //-22-96	NON-CAP		CAP		
Submission number: 13626 A	TSCA Inver	ntory:	Y	N	D
Study type (circle appropriate):					
Group 1 - Gordon Cash (1 copy total)					
ECO AQUATO			•		•
Group 2 - Ernie Falke (1 copy total)					
ATOX SEVOX SEN	WINEUR				
Group 3 -HERD (1 copy each)					
STOX CTOX	EPI	RTOX	ζ		GTO
STOX/ONCO CTOX/ONCO	IMMUNO	CYTO)		NEUF
Other (FATE, EXPO, MET, etc.):					
Notes:		,			
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note to contractors: Separate into 16 records

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0503 INFO REQUESTED (VOL ACTIONS) 0504 INFO REQUESTED (REPORTING RATIONALE) INFORMATION REQUESTED. FLWP DATE 0901 NO INFO REQUESTED DISPOSITION:

(ASP.) REFER TO CHEMICAL SCREENING 0502 INFO REQUESTED (TECH) 6678 CAP NOTICE

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020	ONCO (HUMAN)	91 02 04	0216	EPICLIN	01 62 64	173	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	91 02 04	0242	IMMUNO (HUMAN)	01 02 04
0703	CELL TRANS (IN VITRO)	01 02 04	9120	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 05 0M
020	MUTA (IN VITRO)	91 02 04	6120	HUMAN EXPOS (MONITORING)	01 02 04	974	CLASTO (IN VITRO)	01 05 0M
020	MUTA (IN VIVO)	6 1 6 2 64	0220	ECO/AQUA TOX	0 00 W	0245	CLASTO (ANIMAL)	01 02 04
9070	REPRO/IERATO (HUMAN)	9 62 64	0221	ENV. OCCCREL/FATE	01 02 Q	. 0246	CLASTO (HUMAN)	01 02 04
0707	REPRO/TERATO (ANIMAL)	91 02 04	7770	EMER INCI OF ENV CONTAM	01 02 Q	0247	DNA DAMREPAIR	01 02 04
0208	NEURO (HUMAN)	61 62 64	0223	RESPONSE REQUEST DELAY	01 62 GA	(1740)	PROD/USE/PROC	01 02 04
Se S	NEURO (ANIMAL)	2 2 2		PROD/COMP/CHEM ID	01 02 (47)	0251	MSDS	01 07 04
970	ACUTE TOX. (HUMAN)	9 62 64	B	REPORTING RATIONALE	01 02 0	6530	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	61 62 64		CONFIDENTIAL	01 02			
0212	ACUTE TOX. (ANIMAL)	5 6 6 7	1220	ALLERG (HUMAN)	0 62 E			
	SUB ACUTE TOX (ANIMAL)	60 00 00	8770	ALLERG (ANIMAL)	01 62 t			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 €		•	
0215	CHRONIC TOX (ANIMAL)	01 02 04	0540	METAB/PHARMACO (HUMAN)	01 02 62			

PRODUCTION essarch TOXICOLOGICAL CONCERN: 10% STECIES NUS ONGOING REVIEW YES (DROP/REFER) NO (CONTINUE) NON-CBI INVENTORY YES TRIAGE DATA CAS SR

REFER IN IN MINI

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